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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,826	01/24/2002	Charles E. Tucker	021153-001400US	4198

20350 7590 02/14/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 02/14/2003

X

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 10/057,826	Applicant(s) Tucker et al.
Examiner Celia Chang	Art Unit 1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 12, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4)  Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 19 and 20 is/are allowed.

6)  Claim(s) 1 is/are rejected.

7)  Claim(s) 2-18 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Claims 1-20 are in the case.
2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that it is unclear "what" is the product being made by the process of claim 1. A structural formula without explicitly naming the stereospecificity is inclusive of all the possible stereoisomers under the chemical structure. Contrary to the structural formula, the claim defines the products being "nonracemic diastereomer" of formula I and "stereoisomers" thereof, i.e. are they nonracemic diastereomer only? Are they including other stereoisomers? Or are they inclusive of all the compounds embraced by the structural formula I? Clarification is required.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Please note that it was pointed out supra that the "scope" of the claim being for making "what" product is unclear. If the products being made are all stereoisomers of the structural formula instead of the syn-enantiomer as described on page 7 of the specification, then, critical or essential steps to the process as to how to obtain each nonracemic enantiomer without separation are lacking and must be incorporated into the claim. Since such steps were not found in the specification the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

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4. Claims 2-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims or when the 112 issues of claim 1 can be resolved. Claims 19-20 are allowable.

Claims 2-20 being drawn to a single hydrogenation process in obtaining the *syn*-enantiomer of formula I is neither anticipated nor rendered obvious by the art of record (see 1449 and PTO 892 references) because multiple prior art evidenced that process of obtaining the *syn*-enantiomer of formula I, at the time the invention was made, was hydrogenation employing metal hydride or Pd/C catalytic, followed by stereoisomeric separation through enantiomeric salt formation. No motivation or suggestion as to the one step hydrogenation-separation process using chiral catalyst.

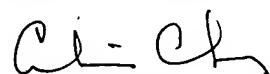
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

WP/Chang

Feb. 12, 2003

  
Celia Chang

Primary Examiner

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